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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/620,820	07/21/2000	Alan D. Attie	960296.97290	4397

7590 05/16/2007

Nicholas J. Seay
Quarles & Brady LLP
P O Box 2113
Madison, WI 53701-2113

EXAMINER	
QIAN, CELINE X	

ART UNIT	PAPER NUMBER
1636	

MAIL DATE	DELIVERY MODE
05/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/620,820	ATTIE ET AL.	
	Examiner	Art Unit	
	Celine X. Qian Ph.D.	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 February 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) *13-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12 and 17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *7/21/00* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *0207*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-17 are pending in the application. Claims 13-16 are withdrawn from consideration for being directed to non-elected subject matter. Claims 1-12 and 17 are currently under examination.

This Office Action is in response to the Amendment filed on 2/16/07.

Response to Amendment

The declaration under 37 CFR 1.132 filed on 2/16/07 is insufficient to overcome the rejection of claims 1-12 and 17 based upon 112 1st paragraph as set forth in the last Office action because: the declaration does not provide sufficient teaching to enable the claimed invention (see reasons discussed below).

The rejection of claims 1-12 and 17 under 35 U.S.C.112 1st paragraph is maintained for reasons set forth of the record mailed on 8/15/06 and further discussed below.

The declaration provided by Dr. Attie asserts that mouse is the most widely used animal model in lipoprotein research as evidenced by Breslow et al., De Winther et al., and Herz et al., and the same broad usage of the mouse is true of all human disease including cancer and neurodegenerative disease. Dr. Attie further asserts that his laboratory have created common inbred mouse strains to replicate the variable susceptibility of all mammals, including human to diabetes as evidenced by reference such as Clee and Attie, 2007. Dr. Attie further asserts that through modification of the expression of genes in mice, mice can be produced to have similar lipoprotein profiles to humans, and there is more than 10,000 published articles with the word mouse and lipoprotein. Dr. Attie further asserts that mouse is a important tool in pharmaceutical industry for validation studies of a drug target. Moreover, Dr. Attie assert that stable integration

of genetic material into a genome and sustained expression of the desired protein is achievable because of the advancement in the field of gene therapy with regard to both viral and non-viral delivery system. Dr. Attie submits that great advance has been made with AAV as evidenced by Warrington and Herzog. 2006. Further, Dr. Attie indicates that Rip reference has demonstrate that delivering a human LPL through AAV achieved normalization of the dyslipidemia of the mice for more than one year. For above reasons, Dr. Attie asserts that the claimed invention is enabled for its full scope.

The declaration has been fully considered but deem unpersuasive. The detailed reason for the non-enablement of the claimed invention was given in the previous office action mailed on 8/15/06. In response to the arguments based upon mouse as a valid model for dyslipidemia, the examiner does not dispute that mouse as a useful research tool in laboratory and pharmaceutical industry, however, the instant claim is not drawn to a method of lowering serum cholesterol level in the mouse only. The claimed scope includes all the mammal including human. The issue is whether the data from the mouse model would extend the predictability of lowering serum cholesterol in an human patient. As discussed in the previous office action, at the time of filing, the technological difficulties in the field of gene therapy (including both safety and efficacy) renders the claimed invention unpredictable with regard to lowering serum cholesterol in human patients based on the mouse model. The cited references for demonstrating the advancement in gene therapy includes those of from Dr. Attie's own laboratory and other authors are dated at 2005, 2006 or 2007, whereas the priority of the instant application is in 2000. The statue requires the teaching from the specification and the relevant art need to provide sufficient support for the enablement of the claimed invention at the time of filing, not after the

filing. For reasons discussed in the previous office action and above, the claimed invention is not enabled by the instant specification.

Response to Arguments

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-12 and 17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In response to this rejection, Applicants argue that the submission of the declaration would overcome the rejection because the declaration establishes that 1) the mouse is a suitable model to mimic human disease in the field of cholesterol research; 2) genetic construct can stably integrated into the genome of a mammal to achieve sustained protein expression to lower serum cholesterol. Applicants thus conclude that the claimed invention is enabled.

The arguments have been considered but deemed unpersuasive. As discussed above, the declaration and teaching from the instant specification only provides support for a method of lowering serum cholesterol by the claimed method in a mouse model. Based on the unpredictability in the art, one cannot extend the predictability of successfully lowering serum cholesterol in human by the claimed method. Applicant's attention is specifically directed to the article Gothardt and Schuster, which is cited in the previous office action, which teaches that

major obstacles must still be overcome before gene therapy for FH becomes a reality despite the success in animal model. As such, for reasons discussed in the previous office action and above, this rejection is maintained.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X. Qian Ph.D. whose telephone number is 571-272-0777. The examiner can normally be reached on 9:30-6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joe Woitach Ph.D. can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Celine X Qian Ph.D.
Examiner
Art Unit 1636

CELINE QIAN, PH.D.
PRIMARY EXAMINER